



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/562,831

06/21/2006

Lene Moller

13323-105005

6753

65989

7590

10/27/2009

KING & SPALDING

1185 AVENUE OF THE AMERICAS

NEW YORK, NY 10036-4003

EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

10/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No. 10/562,831	Applicant(s) MOLLER ET AL.	
	Examiner TAEYOON KIM	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,10,11,14,15,17,18,40,42,43,48-59,61-63,86-100 and 102-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5,10,11,14,15,17-19,21-24,27-30,33-43,48-59,61-63,86-100 and 102-109.

Art Unit: 1651

DETAILED ACTION

Applicant's amendment and response filed on 7/17/2009 has been received and entered into the case.

Claims 2, 4, 6-9, 12, 13, 16, 20, 25, 26, 31, 32, 44-47, 60, 64-85 and 95-100 are canceled, claims 102-109 are newly added, and claims 19, 21-24, 27-30, 33-39, 41 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42, 43, 48-59, 61-63, 86-99, 100 and 102-109 have been considered on the merits. All arguments have been fully considered.

Information Disclosure Statement

The information disclosure statement filed 6/15/2009 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The foreign patent applications of DE 4407875, DE 4119140, DE 3146841, EP 1053758, FR 2679772, FR 2759980, JP 1130519 and JP 62221357 are not in English, And there is no disclosure of a concise explanation of the relevance of the listed references. It has been placed in the application file, but the information referred to therein has not been considered.

Response to Amendment

The objection to the specification has been withdrawn due to the amendment.

The claim objection to claim 11 has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112 has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §102 based on Choi et al. to claim 101 has been

Art Unit: 1651

withdrawn due to the amendment.

Due to the current claim amendment including new claims, the previous claim rejections under 35 U.S.C. §102 and 103 have been modified accordingly.

Claim Objections

Claims 40, 42, 54-59 and 101-109 are objected to because of the following informalities: Based on the current amendment, the term “a derivative thereof” is directed to the hyaluronic acid. If this is the case, the comma should be removed after the term "hyaluronic acid (HA)” in the instant claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 10, 11, 17, 40, 42, 43, 51, 57, 61-63, 86, 89, 92, 95, and 98 stand rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al. (of record).

Choi et al. teach a gelatin-hyaluronic acid (HA) sponge comprising gelatin and HA in a form of sodium hyaluronate (a salt form) in a ratio of 9:1, 7:3 or 5:5, cross-linked chemically with a cross-linking agent such as EDC (1-Ethyl-(3-(3-dimethylaminopropyl) carbodiimide hydrochloride), or physically by thermal heating, and freeze-dried (p.631-632; Materials and Methods). Choi et al. also teach the molecular weight of HA being 1700 kDa and pH being 6.36 (Materials and Methods).

With regard to the limitation of claim 10 drawn to the sponge absorbing less water than

Art Unit: 1651

an absorbable gelatin sponge or the limitation of claim 11 drawn to the ratio between the water absorbed by the composition and the water absorbed by a conventional absorbable gelatin sponge being at the most 0.95, this limitation is merely drawn to the property of the composition rather than the structural limitation to the composition. Since the composition of Choi et al. is considered substantially similar, if not the same, the property of the Choi et al.'s composition is expected to have the same property as the claimed invention.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

Claims 40, 42, 43 and 47 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing

Art Unit: 1651

process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

Claim 1 discloses a new limitation of "wherein said composition is stabilized with dry heat at 110-200°C." This limitation is also considered as a product-by-process limitation as the limitation of claim 40 (i.e. cross-linked by using dry heat at 110-200°C) (see above). Thus, this limitation is not considered to limit the product claim of the current invention.

Thus, the reference anticipates the claimed subject matter.

Response to Arguments

Applicant's arguments in regard to the claim rejection under 35 U.S.C. §102 to claims 1, 3, 5, 10, 11, 17, 40, 42, 43, 51, 57, 61-63, 86, 89, 92, 95, and 98 have been fully considered but they are not persuasive. It is noted that claim rejection under 35 U.S.C. §102 to claim 101 is withdrawn due to the amendment as indicated above.

Applicant alleged that the limitation of process (product-by-process) of the current invention is not taught by the reference. The previous OA (as regard to claims 40, 42, 43 and 47) and the current OA clearly discuss that the limitation drawn to the process of stabilizing or crosslinking with dry heat at 110-200°C does provide any structural limitation to the claimed product other than the composition being crosslinked. Since the instant claims do not positively exclude chemical crosslinking, and there is no evidence showing the difference between gelatin/HA composition produced by chemical vs. physical crosslinking, it is a must to maintain the rejection that the composition of Choi et al. anticipates the claimed invention.

Art Unit: 1651

Applicant is advised to provide structural limitation to distinguish the claimed invention over the prior art and/or submit clear evidence showing the difference, if any, generated by the specific process step (physical crosslinking) of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42, 43, 48-59, 61-63, 86-99 and 101-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. (supra) in view of Della Valle et al. (of record), Moore et al. (of record) and Cascone et al. (1994, J. Mat. Sci.).

The instant claim rejection has been modified from the previous OA due to the new claim amendment.

Choi et al. anticipate the subject matter of claims 1, 3, 5, 10, 11, 17, 40, 42, 43, 51, 57, 61-63, 86, 89, 92, 95, and 98, and therefore, render them obvious (see above).

Choi et al. do not teach that the hemostatic sponge comprising ester of HA (claim 3).

Della Valle et al. teach esters of HA or a salt thereof being used for medical use such as spongy materials (Example 42 in col. 50).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to substitute HA ester or a salt thereof for the sponge composition of Choi et al. as an art-recognized alternative or equivalent to HA.

Although Choi et al. do not particularly teach that the hemostatic sponge being covered

Art Unit: 1651

by a top sheet (claim 14), it is extremely well known in the art that a surgical dressing or sponge employs a plastic film as a cover, and also Moore et al. teach the use of thin plastic film as a cover of surgical dressing or sponge (col. 1, lines 43-55).

Moore et al. teach a surgical sponge covered with a thin plastic film (abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the thin plastic film (cover) of Moore et al. in the sponge of Choi et al.

The skilled artisan would have been motivated to make such a modification because Moore et al. teach that the thin plastic film provides non-sticking, non-sliding surface and high rate of absorption (col. 1, lines 4-13).

The person of ordinary skill in the art would have had a reasonable expectation of success in using the plastic film cover/laminate of Moore et al. in the sponge of Choi et al.

Although Choi et al. in view of Moore et al. do not particularly teach the cover being removable, it would have been obvious to a person of ordinary skill in the art to make composition separable.

M.P.E.P. §2144.04 states if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed

Art Unit: 1651

structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.").

With regard to the limitation drawn to the composition of gelatin and HA being paste or powder, it would have been obvious to a person of ordinary skill in the art to try gelatin-HA sponge into a powder or a paste for different applications. It is considered that the format of the composition as sponge, powder or paste is merely an optional choice known in the art, and a person of ordinary skill in the art would try different, identified and predictable options.

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the limitation of percentage of gelatin and HA in the composition disclosed in claims 48-50, 52-56, 58 and 59, the range of percentage claimed is within the range of percentage for gelatin and HA in the sponge of Choi et al., and therefore, the reference renders the range obvious. Choi et al. teach the ratio of gelatin to HA being 9:1, 7:3 or 5:5, which is

Art Unit: 1651

interpreted as gelatin being 50 to 90% and HA being 10 to 50%. Therefore, the claimed percentage for gelatin being at most 60 to 85% is within the range of gelatin (50 to 90%) taught by Choi et al. Similarly, the claimed percentage for HA being at most 15 to 40% is within the range of HA (10 to 50%) taught by Choi et al.

With regard to the limitation drawn to the composition not comprising a chemical cross-linking agent or residues thereof (claims 101-109), Choi et al. do not particularly teach that the composition is crosslinked without chemical cross-linking agents or their residues.

However, it is well known in the art that gelatin or HA can be crosslinked by heating. Choi et al. teach gelatin can be thermally crosslinked (p.631, right col.) and Cascone et al. teach HA can be crosslinked by thermal treatment at 130°C for HA/PAA sponges (p.770, under “materials and methods”).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try the thermal crosslinking method as taught by Choi et al. and Cascone et al. for the composition of Choi et al. and the resulting composition would not comprise a chemical cross-linking agent or residues thereof.

The skilled artisan would have been motivated to make such a modification because both gelatin and HA are capable of crosslinked via thermal treatment, and thus, thermal crosslinking is considered one of predictable solution known in the art for crosslinking HA and gelatin of Choi et al.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. In the response to the claim rejection, applicant alleged that there is surprising and unexpected property of the gelatin/HA over the conventional gelatin sponges, referring the disclosure in the specification (par. 109). Since Choi et al. teach a gelatin/HA composition, the unexpected and surprising property of the claimed invention, if there is any, should be presented in comparison to the prior art of gelatin/HA composition rather than the conventional gelatin (gelatin only) sponges. Therefore, the argument based on unexpected and surprising property of the claimed invention compared to the conventional gelatin sponge is not considered persuasive.

Applicant discussed the method steps disclosed by Choi et al. utilizing sterilization with ethylene oxide in making gelatin/HA, and its toxic effect. The claimed invention is directed to the product not the process step how to prepare the product. While the claimed invention discloses a process step with regard to the crosslinking process, the claimed invention does not disclose any feature related to sterilization process, or the step of dry heating, even if this is also considered as sterilization step, is disclosed without a toxic chemical such as ethylene oxide. Thus, this argument is based on the feature which is not recited in the rejected claims.

Finally, applicant argued that the product of Choi et al. would necessarily contain chemical cross-linking agents or their residues. This argument is believed to be based on the newly added claims 102-109. Since the above claim rejection has been modified to deal with the new claims, the argument is moot in view of new ground of rejection presented above.

Conclusion

No claims are allowed.

Art Unit: 1651

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651